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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,660	07/20/2000	Marcel Linschoten	1103326 0630	9005

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11/04/2005

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1155 Avenue of the Americas
New York, NY 10036-2787

EXAMINER

COVINGTON, RAYMOND K

ART UNIT PAPER NUMBER

1625

DATE MAILED: 11/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

09/600,660

Applicant(s)

LINSCHOTEN ET AL.

Examiner

Raymond Covington

Art Unit

1625

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2004.
2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 12-26 is/are pending in the application.
4a) Of the above claim(s) 8, 14-17 and 23-26 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 9 and 12 is/are rejected.
7) ☒ Claim(s) 1-7, 13 and 18-22 is/are objected to.
8) ☒ Claim(s) 1-9, 12-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

The restriction requirement has been reconsidered in view of the amendment of 10/20/04 and applicants' comments. However the restriction is deemed sound for reasons of record and will be further clarified below.

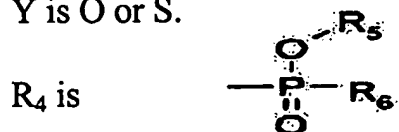
Claims 1, 6, 9 and 18-20 were considered with the original election. Of these claims, claims 1, 6 and 18-20 are objected to but would be allowable if limited as follows:

R₁ is not heterocyclyl containing.

R₂ is not heterocyclyl containing.

X is C(Z)₂ or COHR₇ where Z is non-heterocyclyl with the presently recited provisos.

Y is O or S.

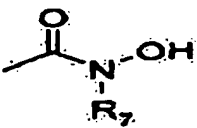


where R₆ is non-heterocyclyl.

Claim 9 is rejected herein below.

Rejoinder

Claims 2-5, 7, 12, 13, 21 and 22 have been rejoined to the extent they depend from or otherwise include all the limitations of claims 1, 6, 9 and 18-20 as noted above. MPEP 821.04.

Claims 8, 14-17 and 23-26 remain withdrawn from consideration as being directed to non-elected subject matter. Claims 8 and 23 are directed to a process where R_4 the group . Claims 14, 16, 24 and 26 are drawn to a composition or

having two active ingredients. Claims 15, 17 and 25 are drawn to kits.

New Rejections

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 is rejected under 35 U.S.C. 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is very confusing as to what is the "scope" being encompassed by the claims. If these are pharmaceutical/veterinary compositions, such compositions must not be "ineffective" nor "toxic".

Therefore, it is recommended that the explicit compound, in its therapeutically effective amount together with inert pharmaceutically acceptable carrier be incorporated in the claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Please note that claim 12 is considered as being a "reach through" claim which contain subject matter to be discovered in the future i.e. any disorder not yet correlated but may be discovered in the future in which inhibition of carboxypeptidase U is required or desired.

Claim 13 are objected to for being a substantial duplicate of claim 1. When two claims in an application are duplicates, or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to reject the other as being a substantial duplicate of the allowed claim. M.P.E.P. 706.03(k). The intended use of the compounds and compositions of claim 13 carry no patentable weight and the claim is therefore duplicate of claims 1 (compound). In this instance, the claims only differ due to

the preamble intended use limitation. Note that intended use limitations are generally not given patentable weight for prior art purposes. In claims drawn to compounds or compositions "If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is necessary to give 'life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim. If, however, the body of the claim fully and intrinsically sets forth the complete invention, including all of its limitations, and the preamble offers no distinct definition of any of the claimed invention's limitations, but rather merely states, for example, the purpose or intended use of the invention, then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation."

Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999). The preamble is solely drawn to an intended use and such use would not materially affect the structure of the compound or the content of the composition. This objection can be overcome by deleting claim 13.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond Covington whose telephone number is (571) 272-0681. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, C. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Raymond Covington
Examiner
Art Unit 1625


RKC


Cecilia J. Tsang
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Technology Center 1600